

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
Gastrointestinal Drugs Advisory Committee (GIDAC)
November 4, 2010
Hilton Washington DC/North, Gaithersburg, MD

Draft AGENDA

The Committee will be asked to discuss whether endoscopically-observed ulcers can serve as the efficacy outcome measure for the labeled indication of risk reduction of NSAID-associated gastric/duodenal ulcers, and for the assessment of upper GI toxicity of NSAIDs and products with novel mechanisms of action.

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| 8:00 a.m. – 8:10 a.m. | Call to Order
Introduction of Committee | Jean-Pierre Raufman, M.D.
Chair, GIDAC |
| 8:10 a.m. – 8:15 a.m. | Conflict of Interest Statement | Kristine Khuc, Pharm.D.
Designated Federal Official,
GIDAC |
| 8:15 a.m. – 8:30 a.m. | FDA Opening Remarks | Donna Griebel, M.D.
Director
Division of Gastroenterology
Products
FDA/CDER |
| 8:30 a.m. – 9:50 a.m. | Sponsor Presentation | Loren A. Laine, M.D.
Professor of Medicine
GI and Liver Diseases Division
Associate Chair of Medicine
Keck School of Medicine
University of Southern California

Andrew Moore, Ph.D.
Pain Research and Nuffield
Department of Anesthetics
University of Oxford
Honorary Professor
School of Health Sciences
University of Wales

Lawrence Goldkind, M.D.
Assistant Professor of Medicine
Uniformed Services University
of Health Sciences
Attending Staff, Division of
Gastroenterology
National Naval Medical Center |
| 9:50 a.m. – 10:05 a.m. | Questions to the Sponsor | |
| 10:05 a.m. – 10:20 a.m. | Break | |

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-Agenda, cont.-

10:20 a.m. – 10:50 a.m. Speaker Presentation

Denis McCarthy, M.D.
(Speaker)
Professor of Medicine and
Biochemistry
University of New Mexico
School of Medicine
Gastroenterologist
Raymond G. Murphy Veterans
Affairs Medical Center

10:50 a.m. – 11:00 a.m. Questions to the Presenter

11:00 a.m. – 11:45 a.m. FDA Presentation

Efficacy Endpoints for
NSAID-Associated Upper GI Injury

Anil Nayyar, M.D.
Medical Officer
Division of Gastroenterology
Products
FDA/CDER

Cross Study Comparisons of
Endoscopically-Diagnosed Ulcers
vs. Upper GI Complications (UGICs)

Eric Brodsky, M.D.
Medical Officer
Division of Anesthesia and
Analgesia Products
FDA/CDER

11:45 a.m. – 12:00 p.m. Questions to the FDA

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 2:00 p.m. Open Public Hearing

2:00 p.m. – 3:00 p.m. Committee Discussion and Questions

3:00 p.m. – 3:15 p.m. Break

3:15 p.m. – 5:00 p.m. Committee Discussion and Questions

5:00 p.m. Adjournment